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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/574,655

03/31/2006

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EXAMINER

OH, TAYLOR V

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

05/29/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/574,655	Applicant(s) ARRUDA ET AL.	
	Examiner Taylor Victor Oh	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 17 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-16 and 19-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

In view of reviewing the claims in details, there are still some issues which are needed to be addressed; thus, the examiner has decided to withdraw the previous office action, and the application is further subjected to another restriction requirement.

LACK OF UNITY

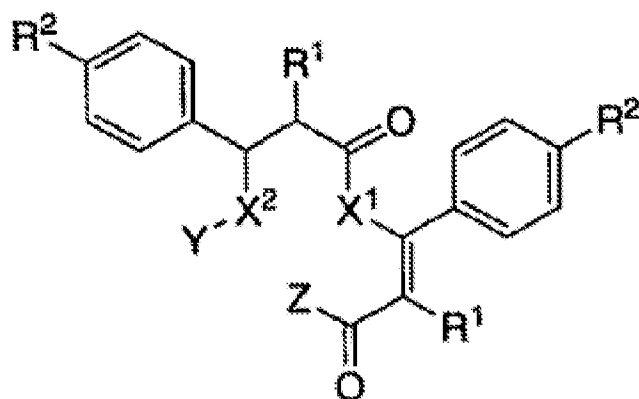
Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group IA, claims 1-16 and 19-20, drawn to a non-heteroaromatic compound of formula I or formula II:

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I

Y is selected from the group consisting of

- (a) hydrogen, and
- (b) acyl,

wherein the acyl group is selected from the group consisting of

- (a) $-\text{C}(\text{O})-\text{C}_{1-6}\text{alkyl}$, optionally substituted with 1, 2 or 3 substituents independently selected from the group consisting of halo, hydroxyl, amino, $\text{C}_{1-3}\text{alkoxy}$, amino $\text{C}_{1-3}\text{alkyl}$,
- (b) $-\text{C}(\text{O})-\text{aryl}$,
- (d) an amino acid;

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X^2 is selected from the group consisting of:

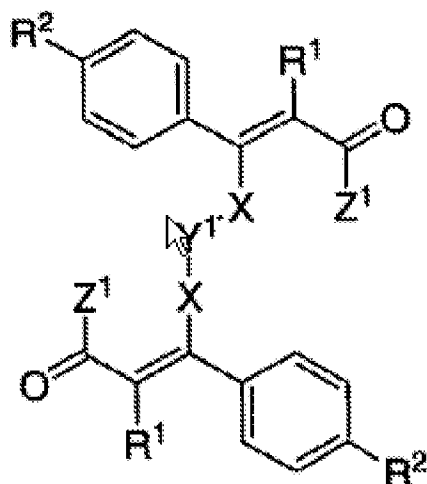
- (a) $-OCH_2-$,
- (b) $-OC(R^3)(R^4)-$,
- (c) $-CH_2\text{-linker-O-}$, and
- (d) $-C(R^3)(R^4)\text{-linker-O-}$;

wherein the carbon end of X^2 is attached to the carbon adjacent to the R^2 -phenyl explicitly shown;

-linker- is selected from the group consisting of

- (a) $-C(O)-(CH_2)_m-O-$,
- (b) $-C(O)-(CH_2)_m(-O-(CH_2)_n)_p-O-$,
- (c) $-C(O)\text{-aryl-O-}$,

wherein m, n and p are each independently integers ranging from 0 to 6;



II

Y^1 is -linker1- , which is selected from the group consisting of

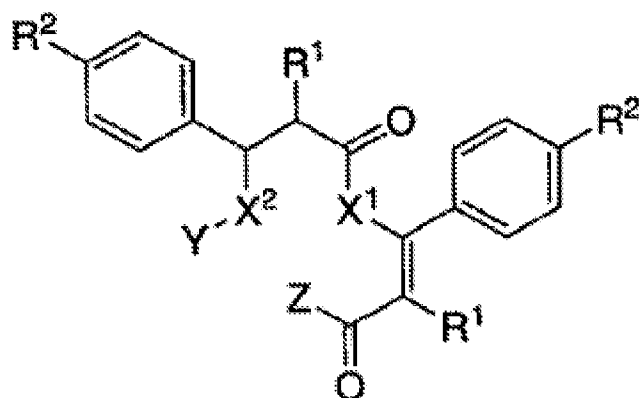
- (a) $-C(O)-(CH_2)_r-C(O)-$,
- (b) $-C(O)\text{-aryl-C(O)-}$,

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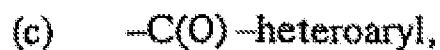
wherein r, s and t are each independently integers ranging from 0 to 6.

Group I B, claims 1-5,8,10-13,15 and 19-20, drawn to a heteroaromatic compound of formula I or formula II:



I

Y is selected from the group consisting of



X² is selected from the group consisting of:

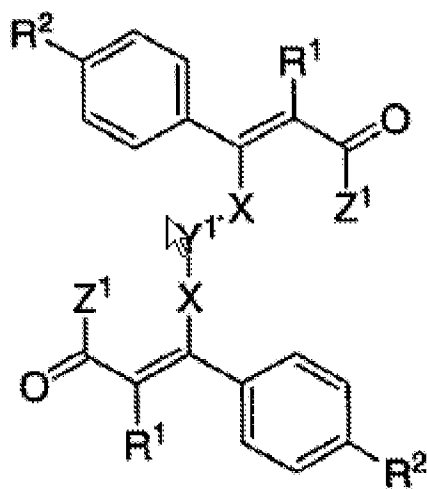


wherein the carbon end of X² is attached to the carbon adjacent to the R²-phenyl explicitly shown;

–linker– is selected from the group consisting of

(d) –C(O)-heteroaryl–O–,

wherein m, n and p are each independently integers ranging from 0 to 6;



II

Y¹ is –linker1–, which is selected from the group consisting of

(e) –C(O)-heteroaryl–C(O)–,

wherein r, s and t are each independently integers ranging from 0 to 6.

Group II (previously withdrawn), claims 17-18, drawn to a method of treating an inflammatory disease, such as rheumatoid arthritis, osteoarthritis, pain, fever, dysmenorrhea, stroke using the formula (I) or (II).

The inventions listed as Group IA, and Group IB do not relate to a single

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general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (" requirement of unity of invention ").

PCT Rule 13.2 states " Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression " special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

In the instant case , the invention of Group IA is directed to the compound of formula I or formula II with a non- heteroaromatic linker, whereas the invention of Group IB is directed to the compound of formula I or formula II with a

heteroaromatic linker , such as **pyridinyl, quinolinyl, isoquinolinyl,**

pyridazinyl, pyrimidinyl, pyrazinyl, quinoxalinyl, furyl, benzofuryl, dibenzofuryl, thienyl, benzothienyl, pyrrolyl, indolyl, pyrazolyl, indazolyl, oxazolyl, isoxazolyl, thiazolyl, isothiazolyl, imidazolyl, benzimidazolyl, oxadiazolyl, thiadiazolyl, triazolyl, tetrazolyl.

These heteroaryl groups are attached to the main core structure. They have different modes of operation , different functions or different effects because each linker has a completely different chemical structure with respect to the core structure. For example, the reactant containing a heteroaryl group has been known

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to have a different reactivity or a different effect in comparison with the one with the non-heteroaryl groups. Therefore, Group I and Group II are unrelated to each other. In addition, each invention has a different use and effect due to unrelated substituents attached to the core of the compounds. Therefore, there is no single general inventive concept and no unity of invention for the method or the process as defined in 37 CFR 1.475.

From this, the Group IB is not required for the invention of Group IA. Therefore, there is no special technical feature between Group IA and Group IB.

Therefore, there is no single general inventive concept and no unity of invention for the method or the process as defined in 37 CFR 1.475.

37 CFR 1.475 states that a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combination of categories:

- a. A product and a process specially adapted for the manufacture of said product;
or
- b. A product and a process of use of said product; or
- c. A product, a process specially adapted for the manufacture of the said product,
and a use of the said product; or
- d. A process and an apparatus or means specially designed for carrying out the
said process; or
- e. A product, a process specially adapted for the manufacture of the said product,
and an apparatus or means specially designed for carrying out the said process.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taylor Victor Oh/
Primary Examiner, Art Unit 1625

5/21/09